Montana State Legislature

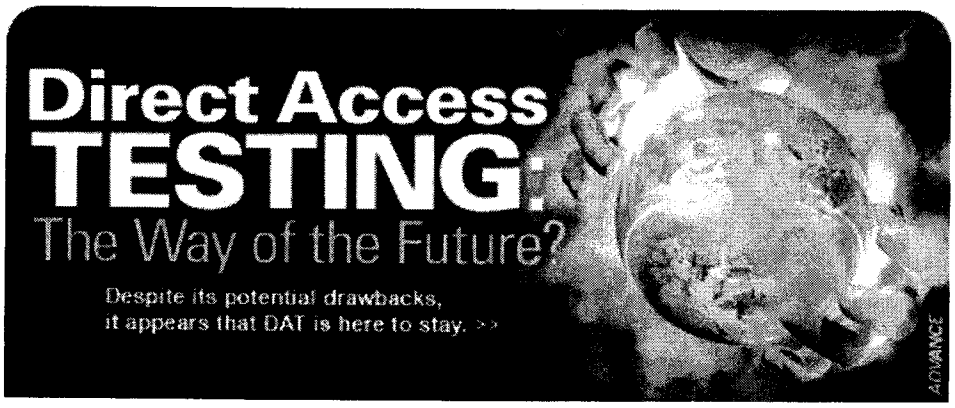
Exhibit Number: 1

This exhibit is in regards to HB 359, It contains several different types of materials to numerous to scan. Therefore only 10 pages has been scanned to aid in your research. They can not be scanned, you may view the original is on file at the Montana Historical Society and may be viewed there

EXHIBIT 1
DATE 2-5-07
HB 359

Physician-Assisted Consumer Testing - *Direct Access*

The Way of the Future?
Endorsement from ASCLS
Trade Association Formed



By Regina Goodrum, MT(ASCP); Elaine Miller, MT(ASCP); Randall Reeves, MS, MT(ASCP); and Hassan Aziz, PhD, CLS(NCA)

Direct Access Testing: The Way of the Future?

Despite its potential drawbacks, it appears that DAT is here to stay.

One of the trends in the healthcare industry is the advent of direct access testing (DAT). DAT represents a de-formalization of traditional healthcare, allowing consumers the opportunity to access the laboratory without having to consult a physician. While it appears unlikely that DAT will supplant traditional healthcare, it does appear that the characteristics which make DAT appealing will propel it to a significant role in the healthcare arena.

Without a Physician

DAT is a service that allows consumers to obtain laboratory-type testing without consulting a physician. It is defined as consumer-initiated testing of human specimens. However, it is up to the consumer to decide what tests should be performed. Laboratory personnel are not licensed to practice medicine; however, "laboratory results not explained to a patient (in writing or in conversation) establish a duty of patient care relationship that is enforced in a court of law."

Even when laboratories employ physicians to meet certain insurance requirements, the extent to which they can advise the patient is limited by both regulatory statutes and potential civil litigation.

However, test results often come with generic information about the test and what the results may mean. Consequently, customers are generally on their own to find a physician to study and evaluate the information to determine an appropriate response.

Formats for DAT
Laboratories involved in DAT retain the same obligations that they have with traditional, physician-ordered tests. In general:

- tests should be performed properly,
- results should be reliable,
- results should be communicated properly to the individual ordering the test, and
- medical information is privileged.

There are essentially four formats for DAT. The first of these is the walk-in laboratory, where trained staff (typically a phlebotomist) is available to assist in sample collection. This method allows for better specimens and, because more complicated samples may be collected, the laboratory can conduct a broader range of tests. Results are reported in a variety of ways, depending upon the test and the policy of the testing lab.

The second of the formats for DAT is the mail-order lab test. These tests usually involve a collection kit, where the patient collects his own sample. Typically, the tests which are susceptible to improper collection (e.g., blood hemolysis) may not be appropriate within this method. Results are often reported via phone or mail.

The third laboratory format available to patients seeking self-diagnosis is in fact a *de facto* form of DAT. This arena involves blood donor processing facilities, where donated blood is screened for a variety of diseases, such as hepatitis and HIV. While donors are discouraged from donating blood to obtain free screening, it is likely that this in fact does occur. In this case, patients are typically notified by mail.

The fourth and final format for DAT is the at-home test kit. In this case, it is up to the patient to collect the sample, perform the test, interpret the results, and determine the appropriate medical response. Obviously, this type of testing includes only those evaluations that are simple to perform and interpret.

Emergence
To a certain extent, DAT has evolved in concert with the development of point-of-care testing and technology. Cost-reduction efforts in the medical field included reduced hospitalization and general de-formalizationpatients were treated on an outpatient basis, often by an assistant or nurse (or even pharmacist). To this effect, the walk-in lab became an extension of outpatient treatment. Meanwhile, technological advances allowed for more reliable test methods that were, in many instances, easier to perform.

Consequently, more and more tests were adapted for use at home, as patients assumed new responsibilities for their healthcare. The FDA has approved numerous kits that allow the patient to either perform the test at home, or to collect the sample at home and mail it to the laboratory for testing. The most common home tests include: pregnancy indicators, ovulation predictors and blood glucose monitors, while home sample collection kits include tests that require a small sample of dried blood (e.g., HIV) or other specimen.

Acceptance
Given the dynamics of the World Wide Web, data is, in essence, available anywhere there is access to the Internet. Presently, no federal statutes restrict test ordering or

release of results to patients. However, many states have introduced legislation to regulate DAT. States that presently have restrictions on DAT include California, Nevada, Utah, Missouri, Arkansas, Illinois, Mississippi, Michigan, New York, Maine, New Jersey, Maryland, Arizona, Oregon, Idaho, Wyoming, North Dakota, Iowa, Kentucky, Tennessee, Alabama, Georgia, Florida, South Carolina, North Carolina, Pennsylvania, Massachusetts, Rhode Island, Connecticut and Hawaii. Puerto Rico also has restrictions.

Advantages

Inherent in this form of healthcare are several advantages. Advocates of DAT point toward cost savings to the consumer, convenience, improved privacy and, most importantly, greater controls of one's own healthcare. The most highly touted advantage of DAT appears to be reduced cost to the consumer. Lab-sponsored Web sites indicate that customers can reduce their medial bills by 40 to 70 percent. Indeed, many employers have relied upon DAT as a low-cost option to screen workers for drug use (with a more formalized test for those who demonstrate positive results). Moreover, physicians will often refer patients who lack the ability to pay for healthcare to this type of testing due to its increased affordability. However, because most insurance plans do not pay for tests unless prescribed by a physician, the potential cost savings are not available to a large segment of the population. Thus, it appears that cost avoidance may in fact be less significant than the convenience and privacy of DAT.

For many customers, the issue of DAT has more to do with convenience than anything else. Within the framework of traditional healthcare, the patient would have to make an appointment (often necessitating an absence from work), spend time traveling to the physician's office, wait for the physician to become available, have the test performed and, in many cases, repeat the entire process several days later to receive the results.

With DAT, consumers can obtain laboratory evaluation with little or no interruption of their daily activities. No doubt, the primary advantages of the home pregnancy test kit and glucose monitoring devices are convenience. Other DATs that appeal because of convenience include mammograms, PSA screening, glucose monitoring and cholesterol testing.

For patients who are embarrassed or concerned with the stigma associated with certain tests (such as screenings for sexually transmitted diseases or drug use), the main advantage of DAT is privacy. Increased discretion is also of concern to many patients who fear that documentation in their medial files may result in denied health or life insurance, or even employment. In particular, a higher level of privacy is often appealing to patients in rural areas, who frequently have nonprofessional relationships with the only healthcare workers available. To this effect, the anonymous nature of DAT provides a vehicle whereby these individuals can determine their health status.

The advantages of DAT involve potentially reduced costs, greater convenience and increased privacy. The primary advantage of DAT, however, may be due to increased accessibility to healthcare services. Consumers who might avoid testing due to financial limitations, time constraints or embarrassment may find DAT more suitable for their circumstances. Thus, individuals who otherwise would be unaware or uninformed of medical issues may be inspired to seek additional medical help or treatment to resolve problems that were revealed *vis a vis* direct access to laboratory testing.

In addition to providing benefits for consumers, DAT also offers advantages for the laboratory. The primary advantages here include putting the labs in new, direct relationships with patients; increased business, and up-front payment for services rendered.

Consumers

DAT appeals to consumers who have had healthcare episodes that have heightened their concern for their health, including those with chronic diseases. To this effect, DAT offers the advantages of price, convenience and privacy. While lower cost often is touted as a way to make healthcare more affordable for the financially disadvantaged, there is evidence to suggest that the largest segment of DAT consumers are middle class patrons who prefer the convenience and/or privacy that this type of testing offers. In fact, since most insurance plans do not cover DAT, these customers actually end up paying more for direct access tests than they would have paid via the traditional format.

Another feature of the DAT market is that nearly all of the business is conducted via the Internet. Even though some laboratories have begun establishing storefront facilities to improve accessibility to consumers, the overwhelming majority of tests are ordered online. Thus, it appears that the typical DAT customer is a middle-class individual who values convenience and privacy, and who prefers to order and schedule tests over the Internet.

Disadvantages

Problems with DAT include potential misinterpretation of test results by the patient, potential lack of confidentiality, lack of proper follow-up in cases where treatment or other action is important or even required by law (such as government notification), and finally, the increased opportunity for fraudulent or incompetent testing. To this effect, many states have enacted regulations that attempt to restrict or even prohibit DAT.

Laboratory directors must be aware that giving patients access to their test results is not as easy as it sounds. Down the road of DAT, there are some disadvantages, concerns, and possible pitfalls for both the laboratory and the patient. One of the biggest problems with DAT is the possibility of the patient misinterpreting test results. Patients may not know the significance of a test and believe that out-of-range results should be interpreted as a disease state and normal results are interpreted as no disease state. A concern of the lab is the extent of result interpretation by laboratory professionals. It is possible that DAT would put the laboratory in a position it has never experienced thus far. Result interpretation and recommendations of treatment by the lab would put them in a role of patient care and bring about new ethical issues and increased liability for the lab. To avoid such a situation, laboratories should include a disclaimer with all DAT reports indicating that the interpretation of test results is a medial matter, which is best undertaken by the patient and his physician. Also, the disclaimer should state firmly that the laboratory only provides information and does not and will not interpret the results.

Responsibility

Another issue of DAT is the privacy and security of results. Many of the test results are received by the patients via the Internet and thus can pose a security problem. The Health and Privacy Project, which is being conducted at Georgetown University, has released a report that questions the privacy and security of some of the 21 healthcare Internet portals researched. They found that visitors to many of the sites were not anonymous because mechanisms such as cookies and click streams allowed third parties to collect information about people without their knowledge or consent. Also, they found that many of the sites don't even follow their own privacy policies. Laboratories that partner with an Internet portal should make sure that all of the services provided through the Internet portal meet the requirements of HIPAA security regulations.

Another concern with DAT is the potential for customers to fail to react properly when presented with important lab information. While failure to consult medical help upon receipt of significant lab findings is one concern, an ever-greater issue revolves around contagious and reportable diseases such as HIV. Such diseases can impact more than

the individual being tested, and positive results often incur responsibility for notification of potentially exposed individuals as well as governmental institutions.

An additional concern with DAT is the potential for fraud and incompetent testing. While the typical brick and mortar facilities of traditional physicians' offices and healthcare agencies are fairly easy to regulate, Internet suppliers are often difficult to track and control. Consumers ordering home test kits may receive results from a lab that uses poor testing procedures.

In some instances, the tests may be complete frauds that provide results that have no validity whatsoever—as in the case of Lei-Home Access HIV, which involved the distribution of fake HIV test kits.

Here to Stay

Some predict that DAT may account for as much as 10 percent of all lab testing within the next few years. While substantial cost savings to consumers have yet to be realized (primarily due to the fact that many insurance companies do not cover DAT), it appears likely that this may change in the near future.

A final concern involving DAT revolves around profitability for the lab. Expenses for advertising, as well as labor costs for medical technologists, put a damper on the supply side of DAT. In essence, DAT does not represent an overnight success, but with determination, it can increase revenue and eliminate the middleman while giving customers a greater role and improved convenience in their healthcare.

For DAT to be profitable, labs will have to develop repeat customers. Another facet, made possible due to advances in technology, is an increased variety of tests available to consumers.

Thus, given the development of a repeat customer base and the potential for an increased variety of testing options, it appears that DAT may indeed represent a lucrative arena for clinical laboratories.

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Above news article recently appeared in:

advance NEWSMAGAZINES www.advanceweb.com

DAT has been endorsed by the American Society for Clinical Laboratory Science: click here to read entire Position Paper.

Document: Consumer Access to Laboratory Testing and Information
Classification: Position Paper
Date: July 2004
Status: Approved by ASCLS House of Delegates July, 2004

The traditional healthcare model in this country places the physician (or appropriate ordering provider) in control of determining what diagnostic and therapeutic monitoring (including laboratory tests) are performed on a patient. In addition, all results of tests and procedures are reported to the physician who assumes the responsibility of relaying the information to the patient. This model is reinforced by Medicare and Medicaid regulation and the laws of a number of states. The general public, however, was introduced to the concept of being directly involved in their own laboratory testing as early as the 1950's with the availability of over-the-counter urine glucose and ketone tests. As the number of diabetics continues to increase, these patients are encouraged to monitor closely their glycemic status in an attempt to decrease the incidence of complications. With diabetes mellitus leading the way, an expansion of over-the-counter testing technology, and a movement for more empowerment of consumers to take responsibility for their own healthcare, has created a major paradigm shift in healthcare, moving from a physician focus to a consumer focus1. One manifestation of this has been direct access testing (DAT) for laboratory services. DAT is also known by a variety of other names including consumer ordered tests, patient-directed testing, direct access to lab services, consumer driven testing, self-ordering, direct-to-consumer and consumer self-orders. It is characterized by the individual paying up-front and out-of-pocket for the service. As of 2004, most insurance companies and other payers are not offering reimbursement. Tests are usually purchased without physician consultation, and the consumer/patient is responsible for any follow up with their clinician2. This is in contrast to the over-the-counter home testing kits available for purchase in pharmacies and other retail outlets. DAT places the clinical laboratory professional in a direct provider relationship with that consumer/patient.

Trade association formed by competitors

John A. Bell, DLS President/CEO, serves on the Board of the newly formed trade organization Direct Access Testing Association (DATA)

In January, 2003, a meeting of competitors sharing a common mission, was held in New Orleans, LA , to form the DIRECT ACCESS TESTING ASSOCIATION *(DATA) An Organization for Direct-to-Consumer Laboratory Testing*

A major purpose for DATA is to establish standards of excellence for members to include:

1. Maintenance of records for five (5) years
2. Formation of a Screening Committee for membership review to ensure that all members meet the standards set by DATA
3. Utilization of CLIA certified labs only
4. Highest standards for confidentiality of results
5. Physician reviewed test results
6. Mandatory follow-up on "out of range" results
7. Adherence to all CLIA, HIPAA, & OSHA regulations
8. Highest standards in phlebotomy including certification
9. Recommendations to DAT customers to have results referred to their healthcare provider
10. DAT members cannot practice medicine, diagnose, or give treatment or medical advise

THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY
POLICY STATEMENT

DIRECT ACCESS TESTING
(POLICY NUMBER 01-02)

YEAR INITIALLY APPROVED: 2001 DATE LAST REAFFIRMED: 10/05 DATE OF NEXT REVIEW: 10/08

POLICY STATEMENT:

In order to ensure optimal patient health outcomes, ASCP believes that patients choosing direct access testing (DAT) should select a CLIA certified laboratory and review all results with their physician.

BACKGROUND AND RATIONALE:

I. Introduction

Direct access testing is becoming an increasingly popular option for patients wishing to monitor their health status and make more decisions about their own health care. DAT can be a useful tool in enhancing the doctor/patient relationship. ASCP believes it is critical for patients to use reliable testing sites, consult with their physician, and pursue appropriate follow-up treatment.

DAT presents a myriad of issues for patients, clinical laboratories, physicians and insurance companies. These issues include, but are not limited to, (A) medical implications including patient understanding of test results, (B) the legal implications and liability issue of DATs, as well as (C) issues involving reimbursement.

II. Medical, Legal and Payment Issues

A variety of medical, legal and payment issues are associated with DAT including the following:

a. Medical Issues

While DAT has the potential to benefit some patients, it may not be appropriate for all individuals, as it has the potential to have a negative impact on health status. Direct access

testing may be beneficial for some individuals. Patients are able to have greater access to tests without dealing directly with physicians or with complex managed care situations. DAT also allows patients to keep certain sensitive test results, such as drug tests or tests for sexually transmitted diseases, out of their medical records or away from potential insurers.[1] However, if the patient's physician is unaware of such problems, he or she cannot provide care for those conditions.

One group that finds DAT particularly appealing has come to be known as the "worried well." These individuals are typically baby-boomer age, highly educated, and want to be more involved in monitoring their own health care status.[2] At a recent meeting the Clinical Laboratory Improvement Advisory Committee (CLIAC) considered a variety of viewpoints on the issue of DAT. During the presentation on physician's views, concerns were expressed about the high costs associated with repeated, unnecessary testing for the worried well as well as their ability to handle "bad" results without the immediate attention of a physician.[3] Thus, depending on the tests ordered, it may be necessary for the DAT laboratory to provide counseling or referral for patients choosing DAT.

1. Interpreting/Understanding Test Results

To ensure that patients understand the results of their direct access tests, laboratories performing DAT should provide patients undergoing testing with easy to comprehend test results.[4] In fact, some states require that the laboratory director be responsible for providing a clear explanation of the results to the patient.*

It can be beneficial for laboratories to make available to the patient, pre-testing information (e.g., the need for fasting, eating or drinking, effect of specific medications, etc.) that may affect test results. If patients are simply given their results and a range of numbers to understand the results, there may be both increased false-negatives and false-positives in test result interpretation.

There is concern among the medical community that tests are being conducted to screen for certain conditions (e.g., expensive total body scans to screen for cancer, a cheek swab test to screen for cystic fibrosis DNA, or an inexpensive cholesterol test that does not screen for triglycerides, an important marker for heart disease risk) in DAT laboratories that would not normally be ordered by a physician. The concern here is that DAT could result in false-positives or false-negatives, possibly leading to increased health care costs as well as adverse impacts on patient health.[5]

2. Consultations

For optimum patient health outcomes, ASCP recommends that patients consult with their physician for proper interpretation of test results. Laboratory testing helps better identify a patient's health status. Clinicians may have access to the patient's family history and other data

* The state of California Health and Safety Code section 123147 states that "a patient's clinical laboratory test results be conveyed in plain language and in oral, written, or electronic form."

that can critically affect test interpretation and can order additional tests to clarify the results or predict risk.[6]

b. Legal Issues

Laws and regulations regarding DAT vary by state, therefore each laboratory performing DAT must operate in accordance with federal and state law. The federal law impacting laboratory testing is the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Although state laws vary, states regulate DAT under one of three basic approaches: states may prohibit DAT entirely, allow DAT in certain situations, or allow DAT without restriction.

1. Federal Law

CLIA does not expressly define who can "order or receive" a laboratory test.[7] Rather, it reserves this authority to the states. According to a Centers for Medicaid and Medicare Services (CMS) interpretation of CLIA, if a state does not prohibit a patient from ordering or receiving laboratory tests, CLIA would not bar an individual from obtaining testing.[8] Thus, in such states DAT would be legal. Clinical laboratories are not required to allow DAT, however, laboratories would need to establish policy as to whether it would provide DAT and which tests, if any, it would provide.

2. State Law

One study found 34 states allow direct access testing in some form.[9] In 20 of these states there are no limitations on DAT, because there are no laws limiting patient ordered testing.* The remaining 14 states have limitations on the types of DAT allowed.** Since this study was published one additional state, Arizona, has changed its legislation to allow for limited direct access testing.[10] These limits involve restricting the types of test that may be ordered via direct access. Several states allow for direct access only for tests classified as waived under CLIA.

Physician's standing orders may also be used to allow testing services through consultation with a doctor. Patients may also be able to obtain laboratory testing by calling a laboratory staffed by a physician who then orders the test.[11] Some states may also have laws regarding the readability of laboratory test results, requiring the results to be provided to patients in clear, easy to understand language.

3. Liability

When patients order their own tests, it is important that the laboratory performing the tests has a strong patient communication and result reporting system. State laws vary on who holds the burden of legal responsibility when it comes to communicating the results of direct access

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* These 20 states are: Alaska, Colorado, Delaware, District of Columbia, Indiana, Louisiana, Minnesota, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, South Dakota, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

** These 14 states are: Arkansas, California, Illinois, Kansas, Maine, Maryland, Michigan, Mississippi, Missouri, Nevada, New Jersey, New York, Puerto Rico, and Utah.